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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,768	12/05/2003	Peter M. Bonutti	2500DV2CN2DV3CN5	3380

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3773

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03/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/729,768	Applicant(s) BONUTTI, PETER M.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 30, 2007 has been entered.

Claim Objections

2. Claim 33 is objected to because an informality, which can be corrected as follows: In line 7, "lest" should be replaced by --least--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 31 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe an inflated, conical inflatable bladder defining a recessed portion at a distal end thereof.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the inflated, conical inflatable bladder defining a recessed portion at its distal end must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 15, 16, 20, and 31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Ginsburg (5,011,488). Ginsburg discloses, at least in figures 1, 2A, and 5C-5E and in col. 6, line 6 to col. 7, line 15; an apparatus including a flexible shaft (18) having open proximal and distal ends defining a lumen therethrough; an inflatable bladder (70) disposed at the distal end of the shaft, the inflatable bladder having a conical shape; and a cannula (12) having an opening at a proximal end portion, an opening at a distal end portion and defining a passage therethrough, the shaft and the inflatable bladder being at least partially disposed within the passage prior to inflation and axially movable therethrough, at least a portion of the inflatable bladder being disposed externally of the passage and adjacent tissue following inflation, such that subsequent axial movement of the shaft may cause dissection of adjacent layers of tissue and create a working space between adjacent layers of tissue, where the inflatable bladder does not substantially stretch when fully inflated, where the inflatable bladder defines recessed portion at a distal end thereof (i.e., the recessed portion is assumed to be the conical side portion of the bladder, which is recessed from the distal

base portion of the bladder) that is configured for receiving tissue during axial movement of the shaft, and where the inflatable bladder is configured to support adjacent layers of tissue (e.g., blood vessel BV) upon inflation.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg (5,011,488). Ginsburg discloses the invention substantially as claimed, but does not specifically disclose that the inflatable bladder operates at pressures from about 10 mmHg to about 1000 mmHg or about 100mmHG to about 1000 mmHG. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the range of pressures as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

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10. Claims 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (3,831,587) in view of Froning (3,875,595). Boyd discloses the invention substantially as claimed. Boyd discloses, at least in figures 1 and 2 and in col. 2, line 40 to col. 3, line 6; an apparatus including a rigid shaft (12) having open proximal and distal ends defining a lumen therethrough; and an inflatable bladder (26) disposed at the distal end of the shaft, the inflatable bladder having a conical shape. However, Boyd does not disclose a cannula having an opening at a proximal end portion, an opening at a distal end portion and defining a passage therethrough, where the shaft and the inflatable bladder being at least partially disposed within the passage prior to inflation and axially movable therethrough, at least a portion of the inflatable bladder being disposed externally of the passage and adjacent tissue following inflation, such that subsequent axial movement of the shaft may cause dissection of adjacent layers of tissue and create a working space between adjacent layers of tissue. Froning teaches, at least in figures 1 and 4 and in col. 1, lines 21-25 and col. 2, lines 27-30; an apparatus including a shaft (47) and an inflatable bladder (46) movable through a cannula (31) to a surgical site. It would have been obvious to one having ordinary skill in the art, in view of Froning, to apply a cannula with the apparatus of Boyd. A cannula would allow the shaft and bladder of Boyd to access a surgical site without undue interference from surrounding tissues and without damaging tissues along the path to the surgical site.

Response to Amendment

11. Applicant's arguments with respect to claims 15-20 and 31-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

March 5, 2008